SIKKIM

GOVERNMENT GAZETTE

EXTRAORDINARY
PUBLISHED BY AUTHORITY

Gangtok **Wednesday 07th March, 2018** **No.85**

GOVERNMENT OF SIKKIM
DEPARTMENT OF FOREST, ENVIRONMENT & WILDLIFE MANAGEMENT
GANGTOK

NOTIFICATION

NO.GOS/FEWMD/PR.SECY-cum-PCCF/220 **Dated: 01/03/2018**

WHEREAS, the State Government is hereby pleased to notify the Quality Manual and shall be deemed to have come into force from the date of publication.

AND WHEREAS, the Quality Manual shall be applicable from the date of its notification in Government Gazette to Quality Control Laboratory of Forest, Environment and Wildlife Management Department, Government of Sikkim.

Dr. Thomas Chandy, I.F.S
Principal Secretary-cum-Principal Chief Conservator of Forest
Forest, Environment and Wildlife Management Department
Government of Sikkim

S.G.P.G. - 85/ Com.9/Gazette/ 100 Cps./ 07. 03.2018

QUALITY MANUAL

FOR

Quality Control Laboratory of Silviculture and Research

Forest, Environment and Wildlife Management Department

Government of Sikkim

Forest Secretariat, Deorali, Gangtok

737102

Quality Manual Review for the Quality Control Laboratory				
Date				
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Attachment 1	Signature Page	23
Attachment 2	Document	24
Attachment 3	Test Method SOP Format	32
Attachment 4	CORRECTIVE ACTION (CA) FORM	37

3.0 Ethics Policy and Data Integrity

The laboratory has developed an ethics policy and established procedures to educate and train personnel in their ethical and legal responsibilities. The laboratory performs routine data review to ensure the records are complete and that they demonstrate ethical conduct. Data integrity procedures are part of this quality manual.

4.0 Document Control

The purpose of the document control system is to ensure that only the most recent revisions of SOPs, worksheets, forms, logs, etc. are available to the appropriate personnel, are timely, and receive the required approvals. All internal regulatory documentation, standard operating procedures, work instructions, service manuals, and product instructions are under document control. The Scientist-In-Charge is responsible for the document control system and keeps a master list of the location of all documents and their current revision. The authorized personnel approve all newly released documents and revised documents. Worksheets, forms, and logbooks are designed to include all information pertinent to the analysis or task performed. Each worksheet, form, and logbook includes a unique identifier. Worksheets and forms have a revision number and effective date.

1. Attachment 3 lists documents in use at [Quality Control Laboratory of Silviculture and Research]

5.0 Subcontracting Sample Analysis and Review of New Work:

5.1 Subcontracting of Sample Analysis

Any subcontracting of work for regulatory reporting shall be subcontracted to laboratories accredited under NABL whenever possible. A chain of custody form is used to track samples from sampling activities to the subcontract laboratory. The chain of custody lists the tests requested for analysis.

5.2 Review of New Work

All new work is initiated by the authorized personnel who delegates responsibilities for the new work according to available resources. Staff will meet prior to initiation of new work in order to determine if appropriate facilities and resources are available. The plan for any new testing shall be reviewed and approved by the Scientist-In-Charge before commencing such work. Facilities and resources are organized to efficiently perform the work. For any new testing requirements, the designated staff shall write a standard operating procedure and demonstrate capability to perform those tests prior to reporting results. The SOP(s) shall be under document control, and a Demonstration of Capability Statement(s)shall be on file.

6.0 Purchasing

Purchasing procedures follow the procurement requirements defined by the guidelines of purchase items of QCL. The technical specifications for equipment and supplies for the laboratory are defined in the laboratory SOPs. The laboratory technician documents the materials or equipment to be ordered. The order is reviewed by the Scientist-In –Charge and approved by the head of the department.

7.0 Complaints

All complaints about the laboratory's activities are documented in a complaint file maintained in the laboratory. The file contains the date and name of the person receiving the complaint, a description of the complaint, source of the complaint, the resolution, and any written material accompanying the complaint. A corrective action form is used to document the complaint.

The authorized person or Scientist-In-Charge [or whoever is responsible] investigates complaints and promptly investigates all areas of activity and responsibility involved. The written results of the investigation including actions taken by the laboratory are reviewed by the Scientist-In-Charge. The results of the investigation are signed and dated by the authorized person.

8.0 Departures from documented policies and procedures or from standard specifications

The Scientist-In-Charge has responsibility for ensuring adherence to the laboratory's policies and procedures. Arrangements for known and controlled departures from documented policies and procedures are allowed. Planned departures do not require audits; however, the departure will be fully documented and include the reason for the departure, the affected SOP(s), the intended results of the departure and the actual results. If the data reported are affected adversely, it will be notified in writing. The procedure used to document any specific departure is the same as the corrective action procedure.

9.0 Corrective Action

(Attachment 4 provides a sample Corrective Action Form that can be used to document corrective actions.)

Corrective actions are the result of concerns regarding work performed by the laboratory, detected problems, or nonconformance and may be from clients, laboratory personnel, assessors or any person or organization with concerns. Records of the concern, nonconformance or complaint and subsequent actions are maintained.

The laboratory takes corrective action whenever unacceptable conditions exist or departures from policies and procedures occur. The following indicators are used to determine unacceptable *conditions:*

- QC samples outside of the established acceptance criteria
- Calibrations outside acceptable criteria
- Equipment failure
- PT studies outside acceptable limits
- Non-conformance identified during internal reviews
- Non-conformance identified on-site inspections
- Non-conformance or problems identified after receiving a question or complaint

Once an unacceptable condition is identified, the laboratory investigates the problem and outlines a corrective action plan.

1.0 Quality Policy Statement

The quality manual is intended for the laboratory operations of the Quality Control Laboratory of Silviculture and Research. This laboratory provides analysis of samples as required by the Forest, Environment and Wildlife Management Department and MOFPI, Government of India and analysis of process samples to ensure proper operation of the Quality Control Laboratory of Silviculture and Research.

Quality Policy Statement

The laboratory management is committed to providing the necessary resources and to defining acceptable laboratory practices in the quality documentation to ensure compliance with ISO 17025 and the permit requirements. Management's policy is to ensure the information in quality documentation is communicated to, implemented and understood by all the laboratory staff performing work in the laboratory.

The quality manual documents the policies and references the procedures to ensure test data generated for submittal to the Forest, Environment and Wildlife Management Department and MoFPI , or any such offices/s are scientifically acceptable as defined by the method performance criteria.

The objectives of the laboratory are to produce data of known and documented quality in order to demonstrate conformance to the permit and laboratory accreditation requirements. The objectives are measured with internal audits and evaluated as part of the management review.

The Quality Control Laboratory of Silviculture and Research(QCL), Forest, Environment and Wildlife Management Department shall provide training, research and development activities on value addition activities, courses, organize workshop, seminar, awareness, consistent with the aims and objectives of the Government for the standardization of natural resources;

The Quality Control Laboratory of Silviculture and Research(QCL), Forest, Environment and Wildlife Management Department shall acquire all such technologies, techniques and standards methods or validated methods to provide the qualitative and quantitative data;

The Quality Control Laboratory of Silviculture and Research(QCL), Forest, Environment and Wildlife Management Department shall collaborate with the designated national and international laboratories and provide a platform for qualitative results;

The goal of the Quality Control Laboratory of Silviculture and Research is to produce data that is in compliance with permit, approval, pertinent regulations of the State and Central Government/s.

2.0 Management

The State Government's policies and planning and dedicated rules and regulations shall govern the Quality Control Laboratory of Silviculture and Research's Management.

Forest, Environment and Wildlife Management Department , GOS is governed by all rules and regulations of the State Government and ensure proper operation of the Quality Control Laboratory of Silviculture and Research.

Further, the staffs of the laboratory shall have a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the overall work of the laboratory.

2.1 Management Responsibilities

Management has the overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations.

Responsible Officials

1. Principal Secretary –cum-Principal Chief Conservator of Forest
   Forest, Environment and Wildlife Management Department
   Government of Sikkim
   Forest Secreriat, Deoarli, Gangtok.

2. C.S Rao , I.F.S
   Chief Conservator of Forest
   Forest, Environment and Wildlife Management Department
   Government of Sikkim
   Forest Secreriat, Deoarli, Gangtok.

3. Principal Scientist / Scientist-In-Charge
   of Quality Control Laboratory of Silviculture and Research
   Silviculture/ HARC/SMPB
   Forest, Environment and Wildlife Management Department
   Government of Sikkim
   Forest Secreriat, Deoarli, Gangtok.

2.2 Job Descriptions

The roles of QCL management are:

- ensuring the quality of data produced by the laboratory.
- training and keeping personnel up to date on laboratory procedures, operation of instrumentation, and laboratory support equipment.
- engaging personnel in the absence of laboratory staff for performing laboratory tasks.
- reviewing and approving any changes to the quality manual and associated quality documentation.
- implementing and overseeing the quality system.
- performing technical laboratory tests and procedures.
- adhering to the quality assurance plan.
- reporting deviations from the quality assurance plan and taking necessary action to bring the quality management system back into compliance.

2.3 Identification of Approved Signatories

See Attachment 2 for signature identifications.

Corrective action may include, but is not limited to, one or all of the following:

- Re-analysis of samples
- Re-calculation of results
- Re-calibration of instrument
- Preparation of new standards
- Re-analysis of blanks
- Dilution of samples
- Additional analyst training
- Replace equipment or supplies
- Re-sampling
- Recalled analysis results or amended reports

SPECIFIC CORRECTIVE ACTION		
TYPE	RECOMMENDED ACTION	DOCUMENTATION
Contaminated Method Blank (Chemistry)	1. Determine source of contamination. 2. Eliminate source of contamination. 3. Re-analyze blank.	Work sheet/log book
LCS outside acceptance limit (Chemistry)	1. Check preparation log for errors 2. Check analysis for errors 3. Check calculations 4. Remake standard or use a different standard 5. Re-analyze standard and all affected samples 6. Run a matrix spike	Work sheet/log book
Positive/Negative controls (Microbiology)	1. Check expiration date of the media 2. Check media preparation 3. Confirm incubator temperatures 4. Prepare new media from same lot. If still not acceptable, prepare new media from different lot 5. Examine analytical technique	Work sheet/log book
Analyst not following the SOP (All methods)	1. Provide additional training 2. Do demonstration of performance 3. Analyze a PT sample	Analyst training fileWork sheet/log book

All corrective actions are documented. A corrective action form may be used for issues that warrant more detailed documentation.

10.0 Records Management

The laboratory has implemented a record management system that allows the historical reconstruction of all laboratory activities. The laboratory keeps a record of each environmental analysis for at least three years as required by environmental regulation.

The laboratory maintains the following records: [such as: personnel records, sample preservation, sample tracking, raw data, maintenance records, copies of reports of analysis, internal audit reports, official documentation and such other as deemed fit etc.]

11.0 Internal Quality System Audits

The Scientist-In-Charge arranges for an internal quality system review annually. The audit is carried out by trained personnel who are independent (if possible) of the activity being audited. The review assesses the requirements of the quality manual against laboratory operations, and laboratory operations against the laboratory's quality manual and SOPs.

The results of the audits are documented in writing. Where audit findings cast doubt on the validity or correctness of the data, the laboratory will take immediate corrective action. Any corrective actions are documented. The Scientist-In-Charge ensures that the corrective actions are discharged within the agreed upon time frame. Any authority whose work was possibly adversely affected shall be notified in writing.

12.0 Management Review

The laboratory management reviews the laboratory quality system and its testing and calibration activities annually to introduce any necessary changes or improvements. The review takes into account the outcome of recent internal audits, inspections by external bodies, the results of interlaboratory comparisons, the results of proficiency tests, any changes in the volume and type of work undertaken, feedback from authorities or others, and corrective actions. The findings and any corrective actions from this review are documented.

13.0 Personnel Training

Before conducting any analysis, each analyst receives training by another analyst or supervisor who has completed training. An analyst in training is supervised by an experienced individual.

In addition to in-house training, additional training may be provided to the analyst in the form of educational courses, professional seminars, and continuing proficiency testing.

Analyst training and performance is considered complete after the analyst has produced a successful initial demonstration of method capability for the analysis for which he/she is responsible. In addition, acceptable results from a proficiency testing sample or internal blind quality control sample are documented for the analyst.

Corrective action may include, but is not limited to, one or all of the following:

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- Re-calibration of instrument
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15.2 Conducting Demonstration of Method Performance

Prior to implementation of a method, the laboratory prepares an initial demonstration of method performance in accordance with method specifications. When the approved method does not specify initial demonstration of performance, the laboratory uses the following guidelines as described in Standard Methods :

- Determination of Limit of Detection (LOD)
- Determination of Limit of Quantitation (LOQ)
- Evaluation of Precision and Bias
- Evaluation of Selectivity

Initial demonstration of method performance must be repeated each time significant changes are made to instrumentation, personnel, or the method. Initial demonstration of performance is documented in Demonstration of Capability records. The process for conducting method validation and/or initial demonstration of performance is included in the [Laboratory SOPs].

16.0 Equipment, Reagents, Supplies, and Reference Materials

All equipment, reagents, supplies, and reference materials necessary for analyses are kept on hand for the specific analysis for which the Quality Control Laboratory of Silviculture and Research performs.

For calibrations of analytical instrumentation, the laboratory uses standards that assure that measurements made by the laboratory are traceable to national standards of measurements or certified reference materials. To achieve traceability of measurements, the laboratory maintains detailed records identifying the analyst(s) responsible for each step of the analytical processes, the origin of all consumables, standards, and reagents used, unique identification of analytical instruments used, calibration records for all equipment used, dates and times of analyses conducted, procedures used for preparing reagents and for analyzing samples, and unique identification of each sample analyzed. Calibration procedures are established for all applicable tests. These procedures are detailed in the SOP for the analysis.

16.1 Laboratory equipment

- All equipment is properly maintained. Procedures for maintenance of equipment are documented in SOPs and equipment manuals.
- Any defective equipment or part is removed from service and labeled until repaired. Equipment or parts are not put back in service until the laboratory demonstrates that it is functioning correctly.
- All routine and non-routine maintenance and repairs are documented in laboratory records.
- Calibration records are maintained for all measuring equipment in laboratory bench sheets and logs.
- Laboratory Support Equipment. All laboratory support equipment is calibrated, or verified, or both, before being put into service, and on a continuing basis. The procedures for the calibration and verification of the laboratory support equipment are found in the SOPs and equipment manuals.

All training is documented and kept on file. At a minimum, documentation includes the name of the analyst, the reference method/SOP, the dates of training, the person providing training, initial demonstration of method capability (if appropriate), and PT results (if appropriate). To document the training, the [QCL] Laboratory uses a training form for each analytical procedure. After successful training and demonstration, the Scientist-In-Charge sign the Demonstration of Capability Form as certification of the analyst's performance.

14.0 Facilities and Environmental Conditions

Testing occurs only within the laboratory. Laboratory space is maintained and monitored to the specifications required. Electronic balances are located away from drafts and doorways and mounted on marble slabs in areas where their use is affected by vibrations.

The laboratory is kept clean. Attention is given to good housekeeping at all times. The laboratory is designed, and activities are conducted, so sample contamination is avoided. The laboratory has adequate lights and ventilation. When required, laboratory temperature and barometric pressure are monitored; the acceptable range is defined in the test method to ensure the proper operation of instrumentation. Appropriate data corrections are made using these monitored values (such as in the BOD method) as defined in Standard Operating Procedures. If environmental conditions are outside the defined method limits, results are qualified.

15.0 Test Methods and Validation

The laboratory maintains an in-house method manual for each certified analyte or test method. The manual may consist of copies of published or referenced methods or standard operating procedures that have been written by the laboratory. Attachment 3 provides an SOP format which includes the sections or references for a test method. The description should include references to the specific method and technology used, the detection limit, and the reporting limits. :

15.1 List of Analytical Tests, Parameters, Method Reference, MDL, and Reporting Limits

ANALYTICAL METHODS				
Analytical test	Analytical Method	REFERENCE METHOD	METHOD DETECTION LIMIT	REPORTING LIMITS

16.2 Reagents and supplies

- Glassware is properly cleaned and maintained as specified in the SOPs. Any cleaning or maintenance requirements specified in the approved test procedure are followed.
- Analytical reagent grade materials, if available, are used by the laboratory.
- The laboratory does not use prepared reagents, standards, or purchased chemicals outside the expiration date of the material.
- All stock and standard solution containers are labeled with content, preparation date, expiration date, concentration, and initials of analyst preparing the solution. For the preparation of reagents, standards, and rinsing glassware, the laboratory uses water of the purity and quality specified by the Standard Operating Procedure, published method, or regulation.

16.3 Reference materials

- To ensure accurate and precise measurements, the laboratory uses reference materials traceable to a national standard of measurement where commercially available or are traceable to certified reference materials.
- The laboratory retains the Calibration Certificates of Reference Materials to demonstrate the traceability.
- The laboratory has a program and procedure for the calibration or re-certification of its reference standards
- The original containers are labeled with an expiration date.

16.4 Listing of Laboratory Equipment and Reference Materials

LABORATORY EQUIPMENT AND REFERENCE MATERIALS			
Name	Brand	Model	Date Placed in Service

16.5 Calibration and Maintenance Procedures and Frequency

CALIBRATION AND MAINTENANCE			
INSTRUMENT	ACTIVITY	FREQUENCY	DOCUMENTATION
Balance	1. Clean 2. Check alignment 3. Service Contract	1. before use 2. before use 3. annual	Work sheet/log book Post annual service date on balance

Calibration of the instruments shall be performed in accordance to the specification. Information such as tolerance, repeatability and such other shall be provided in compliance to the technical requirements to enable further uses.

17.0 Samples

Each sample is uniquely identified from collection to disposal. All samples are identified on the outside of the sample bottle. Each sample is recorded in the sample log.

17.1 Sample Acceptance Policy

After sample collection and transportation to the facility, the laboratory will verify the integrity of the sample by checking for the following items:

- Leakage or breakage.
- Completeness of sample collection logs.
- Correct sample identification.
- Appropriate use of sample labels (such as water resistant) and use of permanent ink.
- Use of appropriate sample containers, adequate volume, preservation, and holding time as required by specific test methods.
- Temperature of samples requiring thermal preservation (checked and recorded at time of sampling).

When the sample received does not meet the acceptance requirements, the condition of the sample is documented and the sample is rejected and re-collected in accordance with the laboratory's written sample acceptance policy.

All samples are logged into the sample log book.

17.2 Storage of Samples in the Laboratory

The laboratory will store samples, sub-samples, and/or other preparation products such as extracts or digestates according to the specified conditions in the approved methodology. All samples, sub-samples, etc. will be protected from all potential sources of contamination, deterioration, or damage.

17.3 Sample Disposal

The laboratory follows its waste management plan or chemical safety program for sample disposal appropriate for the samples handled and wastes generated. Wastewater samples are disposed in the laboratory drain. Any material determined to be hazardous for disposal in a sanitary sewer will be taken to a hazardous disposal site.

18.0 Assuring the Quality of Test Results

The laboratory demonstrates the quality of analytical results through the implementation of a quality control plan.

18.1 Quality Control Samples

Quality control samples run in the laboratory is / are in accordance to the SOPs where information is found.

18.2 Proficiency Testing (PT) Samples

The laboratory obtains PT studies from approved PT provide . PT studies are performed twice per year. The parameters are tested in accordance to the priority list of State Government and Central Government.

PT studies are analyzed in the same manner as regular samples. The same test method procedures and the same internal QC protocol are used when analyzing PT studies.

If the laboratory fails a PT study, an investigation of the cause is conducted. When problems are identified, a corrective action plan is outlined on the corrective action form and actions are completed in a timely manner.

18.3 Split Sampling (Duplicate)

The laboratory collects a duplicate sample and submits the duplicate to a subcontract laboratory for confirmation analysis [on a quarterly, semi-annual, annual basis] to ensure the results reported are accurate. When problems are identified, a corrective action plan is outlined on the corrective action form and actions are completed in a timely manner.

19.0 Reporting the Results

19.1 Procedures to Ensure Reported Data are Free from Errors

Data Validation:
The analyst performing the analysis verifies all data. The data review is to include the following items:

- Calibration of the instrumentation. (Confirm the calibration criteria are met.)
- Quality control data. (Confirm QC meets the acceptance criteria.)
- Calculations. (Check for calculation errors.)
- Documentation. (Check worksheets, logbooks and printouts for accuracy and completeness.)

Before final reporting is done, data are validated by the responsible staff person to verify that all quality control measures are reviewed and evaluated and to ensure the reported data are free from transcription and calculation errors.

19.2 Procedures for Data Qualifiers

Data qualifiers are added to all data not meeting collection, analytical, or internal QC acceptance criteria.

19.3 Procedures for Reporting Analytical Results

Date	Analytical Test	Analytical Method	Reference Method	Method Detection Limits	Reporting Limit/s	Result	Remark

20.0 Glossary

"Acceptance criteria" means specified limits placed on characteristics of an item, process, or service defined in requirement documents.

"Accuracy" means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. Accuracy is an indicator of data quality.

"Aliquot" means a portion of a sample taken for analysis.

"Analyst" or "laboratory technician" means the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

"Analyte" means the substance or physical property to be determined in samples examined.

"Analytical method" means a technical procedure for providing analysis of a sample, defined by a body

"Audit" means a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

"Batch" means samples that are prepared together or analyzed together or both with the same process and personnel, using the same lot or lots of reagents. "Analytical batch" means a batch composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various matrices and can exceed 20 samples. "Preparation batch" means a batch composed of one to 20 samples of the same matrix that meets the criteria in this definition for "batch" and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

"Blank" means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include the following types:

1. Field blank. A blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken.

2. Method blank. A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

"Calibration" means to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

"Calibration curve" means the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

"Calibration standard" means a substance or reference material used to calibrate an instrument.

"Certified reference material" means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

"Corrective action" means the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

"Demonstration of capability" means the procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

"Detection limit" means the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence.

"Document control" means the act of ensuring that documents, and revisions to the documents, are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

"Facility" means something that is built or installed to serve a particular function.

"Finding" means an inspection conclusion that identifies a condition having a significant effect on an item or activity. An inspection finding is normally a deficiency and is normally accompanied by specific examples of the observed condition.

"Holding time (or maximum allowable holding time)" means the maximum time that a sample may be held prior to analysis and still be considered valid or not compromised.

"Internal standard" means a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

"International System of Units (SI)" means the coherent system of units adopted and recommended.

"Laboratory control sample" or "LCS" means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. "Laboratory control sample" or "LCS" may also be named laboratory fortified blank, spiked blank, or QC check sample.

"Laboratory duplicate" means aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.

"Laboratory manager" means the person who has overall responsibility for the technical operation of the environmental laboratory and who exercises actual day-to-day supervision of laboratory operation for the appropriate fields of testing and reporting of results. The title of this person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager.

"Legal entity" means an entity, other than a natural person, who has sufficient existence in legal contemplation that it can function legally, be sued or sue and make decisions through agents as in the case of corporations.

"Limit of detection" or "LOD" means an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte and matrix specific and may be laboratory dependent.

"Limit of quantitation" or "LOQ" means the minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

"Matrix" means the component or substrate that may contain the analyte of interest.

a. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.

b. Non-potable water. Any aqueous sample that has not been designated a potable or potential potable water source. Includes surface water, groundwater, effluents, water treatment chemicals or other extracts.

c. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt water source.

c. Solid and chemical materials. Includes soils, food products, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.

d. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origins.

e. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

d. Nonaqueous liquid. Any organic liquid with less than 15% settleable solids.

f. Solids. Includes soils, sediments, sludges and other matrices with more than 15% settleable solids.

g. Chemical waste. A product or by-product of an industrial process that results in a matrix not previously defined.

h. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"Matrix spike (spiked sample or fortified sample)" means a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

"Matrix spike duplicate (spiked sample or fortified sample duplicate)" means a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

"Method detection limit" means one way to establish a limit of detection, defined as the minimum concentration of a substance (an analyte) that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

"Negative control" means measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

"Preservation" means refrigeration and/or reagents added at the time of sample collection, or later, to maintain the chemical and/or biological integrity of the sample.

"Physical," for the purposes of fee test categories, means the tests to determine the physical properties of a sample. Tests for solids, turbidity and color are examples of physical tests.

"Positive control" means measures taken to ensure that a test or its components are working properly and producing correct or expected results from positive test subjects.

"Precision" means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is an indicator of data quality. Precision is expressed usually as standard deviation, variance or range, in either absolute or relative terms.

"Proficiency test or testing (PT)" means evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

"Proficiency test (PT) field of testing" means the approach to offer proficiency testing by maxtrix, technology/method, and analyte/analyte group.

"Proficiency test (PT) sample" means a sample, the composition of which is unknown to both the analyst and the laboratory provided to test whether the analyst or laboratory or both can produce analytical results within specified acceptance criteria.

"Proficiency testing (PT) program" means the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

"Quality assurance" means an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

"Quality control" means the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

"Quality control sample" or "QC sample" means a sample used to assess the performance of all or a portion of the measurement system. QC samples may be certified reference materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking.

"Quality manual" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

"Quality system" means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control.

"Range" means the difference between the minimum and maximum of a set of values.

"Reference material" means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement test method, or for assigning values to materials.

"Reference standard" means a standard, generally of the highest quality available at a given location.

"Responsible official" means the designated official of the Forest, Environment and Wildlife Management Department, Government of Sikkim.

"Sample tracking" means procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples.

"Sampling" means the act of collection for the purpose of analysis.

"Spike" means a known mass of target analyte added to a blank sample or sub-sample, used to determine recovery efficiency or for other quality control purposes.

"Standard operating procedure (SOP)" means a written document that details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

"Standardized reference material (SRM)" means a certified reference material.

"Statistical Minimum Significant Difference (SMSD)" means the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased.

"Test" means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

"Test method" means an adoption of a scientific technique for performing a specific measurement as documented in a laboratory standard operating procedure or as published by a recognized authority.

"Test sensitivity/Power" means the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis.

"Traceability" means the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

"Validation" means the confirmation by examination and provision of objective evidence that the particular requirements of a specific intended use are fulfilled.

"Verification" means the confirmation by examination and provision of evidence.

"Working range" means the difference between the limit of quantitation and the upper limit of measurement system calibration.

Documents No.... **Effective Date.....**

Revision No...

Attachment 1 **Signature Page**

Signature	Initials	Date
Signature	**Initials**	**Date**
Signature	**Initials**	**Date**

Documents No.... **Effective Date.....**

Revision No...

Attachment 2

1. DOCUMENT

1.1 BIOLOGICAL TESTING

Document Number	Document Name	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	FOOD AND AGRICULTURAL PRODUCTS			
1.	Milk, Milk Products			
SOP1	(Milk Raw, Sterilized, Pasteurized, Tonned, Flavoured, Cream, Butter, Infant Milk & Milk Substitutes And Other Related Products, Milk Powder, Skim, Partly Skimmed, Whole Condensed Milk, Dahi, Butter Milk, Paneer Cheese & Cheese Products, Ice-Cream, Frozen Dessert)	Total Plate count	IS:5402-2002	≥ 1cfu/ml OR e" 10 cfu/gm
SOP2		Yeast & Mould Count	IS:5403-1999	≥ 1cfu/ml OR e" 10 cfu/gm
SOP3		Coliform Count	IS:5401(P-I)-2002	e"1cfu/ml OR e" 10 cfu/ gm Present/Absent in 0.1gm or ml Present/Absent in 1gm or ml
SOP4		E-coli(Isolation)	IS:5887(P-I)-2000	Preent/Absent in 1.0gm or ml OR Present/Absent in 0.1 gm
SOP5		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm or ml
SOP6		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm Present/Absent in 1gm or ml Present/Absent in 0.1gm or ml
SOP7		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm or ml
SOP8		Listeria monocytogenes	IS:14988(P-II):2005	Present/Absent in 1gm or ml
SOP9		Antibacterial substances (b-Lactam)	Delvotest-SP	Detected/ not detected
2. Fruits & Vegetable Products				
SOP10	Fruits & Vegetable Products Pickles, Fruit Juices, Canned fruits, Fruit Pulp, Salad, Raw Vegetable, Ketchup, Jam	Total Plate count	IS:5402-2002	≥ 1cfu/ml OR e" 10cfu/gm
SOP11		Yeast & Mould Count	IS:5403-1999	≥ 1cfu/ml OR e" 10 cfu/gm
SOP12		Coliform Count	IS:5401(P-I)-2002	≥ 1cfu/ml OR e" 10 cfu/gm
SOP13		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in 25gm or ml

	& jellies, Sauce, Ready to serve fruit beverages			
SOP14		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25gm or m
SOP15		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP16		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm or m
1.	Food Grains, Pulses, Cereals, Solvent Extracted Edible Flours & Related Products			
SOP17	Food Grains, Pulses, Cereals, Solvent Extracted Edible Flours & Related Products (Wheat, Rice, Pulses, Besan, Maida, Suji & Related products, Solvent Extracted Soya Flour, Solvent Extracted Groundnut Flour, Solvent Extracted Sesame Flour, Solvent Extracted Coconut Flour, Isabgul Husk & powder)	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP18		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP19		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP20		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in 25gm
SOP21		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm
SOP22		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP23		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
SOP24		Folic Acid	ELISA	0.16-1.28 mg /100g x DF
SOP25		Vitamin B12	ELISA	0.03-0.18 mg /100g x DF
2.	Whole & Ground Spices & Condiments & Mix Masala			
SOP26	Whole & Ground Spices & Condiments & Mix Masala (Chilly, Turmeric, Coriander, Cumin, Ajwain, Fennel, Mustard, Pepper, Ginger	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP27		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP28		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP29		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in 25gm

5.	Meat & Meat Products			
SOP30	Meat & Meat Products	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP31		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP32		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP33		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in gm
SOP34		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm
SOP35		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP36		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
2.	Vitamins in Premix / Food / Food Supplements / Health Food & Supplements/ Dietary Foods [Raw, Semi processed & Processed] & Cattle Feed			
SOP37	Vitamins in Premix / Food / Food Supplements / Health Food & Supplements/Dietary Foods [Raw, Semi processed & Processed] & Cattle Feed	Folic Acid	ELISA	0.16-1.28 mg /100g x DF
SOP38		Vitamin B12	ELISA	0.03-0.18g /100g x DF
SOP39		Vitamin B6	ELISA	2-120mg / 100g x DF
SOP40		Vitamin B5 (Pantothenic Acid)	ELISA	0.04-0.24 mg/100g x DF
SOP41		Vitamin H (Biotin B7)	ELISA	0.08-0.72 mg/100g x DF
SOP42	Dehydrated Onion, Dehydrated Garlic, Curry Powder, Mix Masala Chana Puri Masala, Pav Bhaji Masala)	Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm
SOP43		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP44		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
3.	Ready to Eat Products (Namkeen, Ready to eat food, bakery products, snacks, sweets, frozen food)			
SOP 46	Ready to Eat Products (Namkeen, Ready to eat food, bakery products, snacks, sweets, frozen food)	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP47		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP48		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP49		E-coli (Isolation)	IS:5887(P-I)-2000	Present/Absent in 25gm
SOP50		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm

SOP51		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP52		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
4.	Tea & Tea Product			
SOP53	Tea & Tea Product	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP54		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP55		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP56		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in 25gm
SOP57		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm
SOP58		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP59		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
5.	Meat & Meat Products			
SOP 60	Meat & Meat Products	Total Plate count	IS:5402-2002	≥ 10cfu/gm
SOP61		Yeast & Mould Count	IS:5403-1999	≥ 10cfu/gm
SOP62		Coliform Count	IS:5401(P-I)-2002	≥ 10cfu/gm
SOP63		E-coli(Isolation)	IS:5887(P-I)-2000	Present/Absent in gm
SOP64		Salmonella	IS:5887(P-III) -1999	Present/Absent in 25 gm
SOP65		S.aureus	IS:5887(P-II)-2000	≥ 1cfu/ml OR e" 10 cfu/gm
SOP66		Shigella	IS:5887(P-VII)-1999	Present/Absent in 25gm
II.	SWAB			
SOP67	Equipment, Handler, Cooking Accessories, Cooking Platform.	Total Bacterial Count	As per In-house testing method GL/WI/M-118	≥ 1 cfu/area
III.	WATER			
SOP68	Drinking Water IS:10500:1991 Reaff 1993 Ice Manufacturing Water IS 3957-1966 Reaff 1989 (*Please see the Note below)	MPN / Coliform	IS:1622-1981 Reaff. 2003	≥ 2 MPN/100 ml
SOP69		E-Coli (By MPN)	IS:1622-1981 Reaff. 2003	≥ 2 MPN/100 ml
SOP 70	Packaged Drinking Water S:14543:2004 Packaged Natural Mineral Water IS:13428:2005 (*Please see the Note below)	Escherichia coli	IS:15185-2002	Present or Absent / 250ml

SOP71 SOP72		Coli form bacteria Faecal streptococci	IS:15185-2002 IS:15186-2002	Present or Absent / 250ml Present or Absent / 250ml
SOP73		Sulphite reducing anaerobes	IS:13428(Ann-C) -2005	Present or Absent / 50ml
SOP74		Pseudomonas aeruginosa	IS:13428(Ann-D) -2005	Present or Absent / 250ml
SOP75		Aerobic microbial count(at 20-22°C for 72 hrs and at 37°C for 24 hrs)	IS: 5402-2002	≥ 1 cfu / ml
SOP76		Yeast & Mould	IS: 5403-1999* / IS:15188:2002	Present or Absent / 250ml
SOP77		Salmonella	IS:15187-2002	Present or Absent / 250ml
SOP78		Shigella	IS:5887(P-7)-1999* / IS:15188:2002	Present or Absent / 250ml
SOP79		Vibrio cholerae	IS:5887(P-5):1976* / IS:15188:2002	Present or Absent / 250ml
SOP80		V. parahaemolyticus	IS:5887(P-5):1976 */ IS:15188:2002	Present or Absent / 250ml
SOP81	Swimming Pool Water, IS: 3328-1993	Staphylococcus aureus	IS: 5887(P-2)-2000*/ IS:15188:2002	Present or Absent / 250ml
SOP82		Standard Plate Count	Annex A of IS 3328-1998	≥ 1 cfu / ml
SOP83		MPN / Coliform	IS: 1622-1981 Reaff 2003	≥ 2 MPN/100 ml

1.2 CHEMICAL TESTING

Document Number	Specific Test Performed/Documents Name	Test Method Specifications against which performed	Rage of Testing/ Limit of test are operating
SOP84	Calcium	IS 15121-2002	1ppm MDL
SOP85	Phosphorus	IS 14828-2000	>0.1 %
SOP86	Magnesium	IS 15121-2002	1pppm MDL
SOP87	Saly as (Sodium chloride)	IS : 7874(PART ii) -1975	0.5-20%
SOP88	Iron	IS; 15121-2002	1PPM MDL
SOP89	Manganese	IS: 15121-2002	1PPM MDL
SOP90	Cobalt	IS: 7874(Part II) -1975	1PPM MDL
SOP91	Zine	IS: 15121-2002	1PPM MDL
SOP92	Lead	AOAC -999-11-1999	1PPM MDL
SOP93	Moisture	IS: 4941-1994-2002	0.1-40%
SOP94	Total Reducing Sugars	IS: 4941-1994-2002	0.5-90%
SOP95	Total Ash	IS: 4941-1994-2002	0.1-50%
SOP96	Acidity	IS: 4941-1994-2002	0.05-1.0%
SOP97	Optical density at 660 nm	IS: 4941-1994-2002	0.2-1,5%
SOP98	Specific gravity	IS: 4941-1994-2002	0.5-1.5%
SOP99	Fiehe's Test	IS: 4941-1994-2002	Qualitative
SOP100	Sucrose	IS: 4941-1994-2002	0.5-95%
SOP101	Fructose glucose ratio	IS: 4941-1994-2002	0.5-1.0%
SOP102	Sulphated ash	IS: 1679	0.1-40%
SOP103	Lead	IS: 1679/ aoac/997, 15-1997	1 ppm MDL
SOP104	Plarization	IS: 1679/ 1985	Upto 99.95%
SOP105	Alcohol soluble extract	IS: 1797	0.2 -20%
SOP106	Acidity (as Anhydrous Citric acid)	IS:13242-1991	0.2-20%
SOP107	Cold Water soluble extract	IS: 1797/SP:18-Part VII	0.2-40%
SOP108	Lead	IS: 2860/ AAS /AOAC	11ppm MDL
SOP109	Total Ash	IS:1797/1985	0.2-20%
SOP110	Water soluble ash	IS:1797/1985	0.1-50%
SOP111	Acid insoluble Ash	IS:1797/1985	0.1-40%
SOP112	Moisture content	IS:1797/1985	0.1-40%

SOP113	Crude Fibre	IS:1797/1985	0.1-40%
SOP114	Calcium	IS:1797/1985	1PPM MDL
SOP115	Volatile oil	IS:1797/1985	1.0-25%
SOP116	Moisture and insoluble impurities	IS: 548 –part1-1964	0.1-40%
SOP117	Acid value	IS: 548 –part1-1964	1-150%
SOP118	Iodine value	IS: 548 –part1-1964	10-200%
SOP119	Saponification value	IS: 548 –part1-1964	10-150%
SOP120	Colour	IS: 548 –part1-1964	1 hazen and above
SOP121	Flash point	IS: 1448-part 21/1992	10-360°c
SOP122	Cloud point	IS: 11069-1984	Upto 30°C
SOP123	Insoluble bromide Test	IS: 4276-1977	Up to 0.5%
SOP124	Refractive index	IS:548-part I / 1994	1.33 -1.56 %
SOP125	Specific gravity	IS:548-part I / 1994	0.5-1.5%
SOP126	Unsaponifiable matter	IS:548-part I / 1994	0.5%
SOP127	Phosphorus	IS: 4276-1977	>0.1%
SOP128	Bellier Turbity test	IS: 548-part II / 1964	15-41°C
SOP129	Sulphated Ash	IS: 6287-1985	0.1-40%
SOP130	Acid InsolubleAsh	IS: 6287-1985	0.1-5%
SOP131	Reducing sugars	IS: 6287-1985	0.5-90%
SOP132	Acenaphthylene	ALPHA 2000 , (6440B)	100ppb
SOP133	Anthracine	ALPHA 2000 , (6440B)	100ppb
SOP134	Benzo(A) anthracene	ALPHA 2000 , (6440B)	100ppb
SOP135	Benzo (A) pyrene	ALPHA 2000 , (6440B)	100ppb
SOP136	Benzo (B) Fluranthene	ALPHA 2000 , (6440B)	100ppb
SOP137	Benzo (G.H.I) Perylene	ALPHA 2000 , (6440B)	100ppb
SOP138	Phytochemical analysis	Harborne, 1973	

1.3 Other SOPs

As the State Government has undertaken several measures for the qualitative improvement of forest, environment, wildlife, organic forest produces, quality organic bioresources, farm products and such other products. The "QCL" shall act as the State Nodal Laboratory for the analysis of forest produces and such other related activities as may be referred to it including nutriceutical and cosmeceutical item testing to harness National and International markets and provide technical information on forest produces and natural resources.

In compliance to the test/s of the given purposes, the appropriate or prescribed standard methods or published methods shall be adopted for the qualitative and quantitative results.
It shall be updated according to the test method SOP format in attachment 3.

Documents No.... **Effective Date.....**

Revision No...

Attachment 3 **Test Method SOP Format**

HEADER

SOP # Effective Date:
Revision #:
Approval of designated authority: _____ Date:_____

SOP NAME

1. Identification of test method
2. Applicable matrix or matrices
3. Method detection limit
4. Scope and application, including components to be analyzed
5. Summary of the test method
6. Definitions
7. Interferences
8. Safety
9. Equipment and supplies
10. Reagents and standards
11. Sample collection, preservation, shipment and storage
12. Quality control
13. Calibration and standardization
14. Procedure
15. Calculations
16. Method performance
17. Pollution prevention
18. Data assessment and acceptance criteria for quality control measures
19. Corrective actions for out of control data
20. Contingencies for handling out of control or unacceptable data
21. Waste management
22. References
23. Any tables, diagrams, flowcharts, and validation data

Documents No.... **Effective Date.....**

Revision No...

ADDITIONAL NOTES:

Changes to SOPs should be documented with a Change Log that accompanies the current version and captures the timeline and content of changes. A sample format is below:

Date:	Revision #:	Summary of Changes:	Submitted By:	Approved By/Date:	Effective Date:

Documents No.... **Effective Date.....**

Revision No...

Attachment 4 **CORRECTIVE ACTION (CA) FORM**

LABORATORY NAME: Quality Control Laboratory of Silviculture and Research

ID.....

DEPARTMENT OR ANALYSIS TYPE:

_____

EVENT NAME / CATEGORY___ _____LOG # _____

[Categories: QC failure; PT failure; customer complaint; sample mishandled by lab; instrument malfunction; reporting error, etc. THE LOG NUMBER IS A UNIQUE IDENTIFIER ASSIGNED BY THE LABORATORY.]

RESPONSIBLE OFFICIAL: _____

PERSON COMPLETING CA FORM (NAME, TITLE):

_____ DATE: _____

[The office of QCL retains all Corrective Action reports in an organized system. The Log # is used to ensure all CAs are uniquely identified. Filing records by Log # is recommended; complete records will account for all Log #s. The Event Name/Category is used to track CAs for trends/patterns.]

RECORD INFORMATION BELOW OR ATTACH ADDITIONAL SHEETS. PROVIDE DOCUMENTATION WHENEVER

EVENT DESCRIPTION:

EVENT RESPONSE / INVESTIGATION STEPS:

ROOT CAUSE DETERMINATION:

Documents No.... **Effective Date.....**

Revision No...

CORRECTIVE ACTION (CA) FORM (cont'd)

ACTION(S) TAKEN TO RESOLVE ISSUE AND PREVENT RECURRENCE: Include SOP revision, staff training, purchase of standards or equipment, document/form revision, etc.

Corrective Action(s)	Contact Person Responsible	Proposed Implementation Date	Date Completed	Evidence Of Completion
Additional Comments/Supplemental Information:				

Submitted By:		Date:
Reviewed By:	Responsible Official	Date:

By signature and comments below, the QA Manager and Laboratory Director or Technical Manager approve this corrective action plan and the proposed implementation date(s) given. The QA Manager or designee will provide follow-up until the corrective action is closed with documentation/evidence of completion as noted above.

Approved By:		Date:
Reviewer Comments or Additional Actions Recommended:		

Closing the Corrective Action: The Scientist-In-Charge is responsible for effectiveness review. The CA should stay OPEN for a sufficient time to ensure all stated actions were taken and address/solve the initial issue.

Documents No.... **Effective Date.....**

Revision No...

Corrective Action Closed By:

Signature: _____ Date:_____

Documents No.... **Effective Date.....**

Revision No...

GOVERNMENT OF SIKKIM
FOREST, ENVIRONMENT AND WILDLIFE MANAGEMENT
QUALTIY CONTROL LABORATORY OF SILVICULTUREAND RESEARCH
DEORALI, GANGTOK- 737102

Ref. No..... Date:.....

REPORT OF .....

TEST CERTIFICATE

Reference Number:..... Document Number:.....

Particulars of Sample Analyzed:.....

Client Name:	Sampling Protocol:
Address:	Date of Sampling:
Contact Person:	Date of Receipt:
Collection Point:	Date of Analysis:
Sample Description:	Date of Report:
Senders Letter No and Date:	Sample Drawn by:

RESULTS OF ANALYSISChemical Parameters

Sr No	Particulars	Units	Methods	Result/s	Desirable Limits

Biological Parameters

Sr No	Particulars	Units	Methods	Result/s	Desirable Limits

Remark / Management Recommendation:

Authorized Signatory

Note:

1. This report is valid for the tested sample only.
2. Test Report shall not be reproduced except in full with written approval of the head of department.
3. This report should not be used for advertisement / judicial purpose.